California Medical Device Recall Information

Recall Name
Focus Diagnostics Recalls Simplexa™ Herpes Simplex Virus 1 & 2 Direct and Simplexa™ Group A Strep Direct Kits Containing the Direct Amplification Discs Due to Potential for Inaccurate Test Results

Recall Date	Product Description	Recalling Firm	Recall Reason
2/10/16	Kits containing Direct Amplification Discs: • Simplexa™ Herpes Simplex Virus 1 & 2 Direct Kits • Simplexa™ Group A Strep Direct Kits	**Focus Diagnostics, Inc.** Cypress, CA	*Potential for leakage into adjacent wells causing cross-contamination and inaccurate test results.*
Recall Class	**Product Identification**	**Distribution**	**Affected Dates**
I	Model Numbers: MOL2150, MOL1451, MOL1452, MOL2850, MOL1455 Suspect Lot Numbers: **2140887, 2140332, 2127423, 2159531, 2165240, 2173319, 2169601, 2176090, 2181518, 2181519, 2198924, 2163486, 2171337, 2176091, 29230, 29232, 29233, 29453, 29670, 29691, 29671, 29845, 29847, 29848, 29690, 29669, 29692, 29846, 151682, 151685, 151686, 151871, 151918, 151996, 151997, 152055, 152107, 152108, 152359, 151917, 151915, 151995, 151998, 152057, 152056**	**CA**, nationwide	Distributed between: **Sep 16, 2015** and **Feb 11, 2016**

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm495875.htm